125. The composition of claim 64, wherein the biologically active agent is calcitonin.

126. The composition of claim 64, wherein the biologically active agent is cromolyn sodium.

a10 cont.

127. The composition of claim 64, wherein the biologically active agent is an antimicrobial.

REMARKS

Claims 6, 16, 25, 43, 53, 62, 80, 90 and 99 have been amended to include the active agents low molecular weight heparin and antimicrobials. Support for this amendment is found at page 15, lines 14 and 18, of the specification. Claims 112-127 have been added. Support for new claims 112-127 is found at page 15, lines 4-19, of the specification. Accordingly, claims 1-127 are pending and at issue.

The Examiner has required restriction to one of the following groups of claims under 35 U.S.C. §121:

I. Claims 1-12, 38-49 and 75-86 drawn to a method of delivery; and

II. Claims 13-37, 50-74 and 87-111 drawn to a composition.

The applicants respectfully traverse this restriction requirement.

The compositions recited in the claims of Group II are administered by the methods recited in the claims of Group I to facilitate the delivery of biologically active agents. Once the patentability of the compositions recited in the claims of Group II is established, methods of using the compositions, such as those recited in the claims of Group I are also patentable. *In re Ochiai*, 37 USPQ 2d. 1127 (Fed Cir. 1995).

M.P.E.P. §821.04 states that "if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined." Therefore, in the event that the restriction requirement is not withdrawn, applicants reserve the right to have the method claims of Group I rejoined after the product claims are found to be allowable.

In order to fully responsive, applicants hereby provisionally elect the claims of Group II, claims 13-37, 50-74 and 87-111, for further prosecution.

The Examiner has also required election of one of the following species of the claimed invention:

Group I. Methods of delivery

A. By the subcutaneous route (claims 1-12) utilizing the following species of perturbant:

1. Proteinoid (claims 1-7)

2. Acylated amino acid and acylated polyamino acid (claim 8)

3. Sulfonated amino acid and sulfonated polyamino acid (claim 9)

4. Acylated aldehyde of amino acid and acylated aldehyde of polyamino acid (claim 10)

5. Acylated ketone of amino acid and acylated ketone of polyamino acid (claim 11)

6. Carboxylic acid (claim 12)

B. By the sublingual route (claims 38-49) utilizing the following species of perturbant:

1. Proteinoid (claims 38-44)

2. Acylated amino acid and acylated polyamino acid (claim 45)

3. Sulfonated amino acid and sulfonated polyamino acid (claim 46)

4. Acylated aldehyde of amino acid and acylated aldehyde of polyamino acid (claim 47)

5. Acylated ketone of amino acid and acylated ketone of polyamino acid (claim 48)

6. Carboxylic acid (claim 49)

C. By the intranasal route (claims 75-86) utilizing the following species of perturbant:

1. Proteinoid (claims 75-81)

2. Acylated amino acid and acylated polyamino acid (claim 82)

3. Sulfonated amino acid and sulfonated polyamino acid (claim 83)

4. Acylated aldehyde of amino acid and acylated aldehyde of polyamino acid (claim 84)

5. Acylated ketone of amino acid and acylated ketone of polyamino acid (claim 85)

6. Carboxylic acid (claim 86)

Group II. Compositions and methods for preparing the same

A. A subcutaneously deliverable composition and method for preparing the same (claims 13-37) utilizing the following species of perturbant:

1. Proteinoid (claims 13-17, 23-26, and 32-37)

2. Acylated amino acid and acylated polyamino acid (claims 18 and 27)

3. Sulfonated amino acid and sulfonated polyamino acid (claims 19 and 28)

4. Acylated aldehyde of amino acid and acylated aldehyde of polyamino acid (claims 20 and 29)

5. Acylated ketone of amino acid and acylated ketone of polyamino acid (claims 21 and 30)

6. Carboxylic acid (claims 22 and 31)

B. A sublingually deliverable composition and method for preparing the same (claims 50-74 and 111) utilizing the following species of perturbant:

1. Proteinoid (claims 50-54, 60-63, 67-74, and 111)
2. Acylated amino acid and acylated polyamino acid (claims 55 and 64)
3. Sulfonated amino acid and sulfonated polyamino acid (claims 56 and 65)
4. Acylated aldehyde of amino acid and acylated aldehyde of polyamino acid (claims 57 and 66)
5. Acylated ketone of amino acid and acylated ketone of polyamino acid (claims 58 and 67)
6. Carboxylic acid (claims 59 and 68)

C. A method for preparing an intranasally deliverable composition (claims 75-86) utilizing the following species of perturbant:

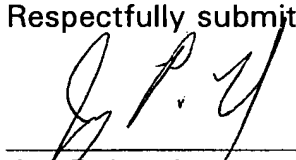
1. Proteinoid (claims 87-91, 97-100, and 106-110)
2. Acylated amino acid and acylated polyamino acid (claims 92 and 101)
3. Sulfonated amino acid and sulfonated polyamino acid (claims 93 and 102)
4. Acylated aldehyde of amino acid and acylated aldehyde of polyamino acid (claims 94 and 103)
5. Acylated ketone of amino acid and acylated ketone of polyamino acid (claims 95-104)

6. Carboxylic acid (claims 96 and 105)

Applicants hereby elect the claims of Group II(B)(2) (claims 55 and 64), a sublingually deliverable composition having an acylated amino acid or acylated polyamino acid perturbant and method for preparing the same.

An early and favorable action on the merits, is now respectfully requested.

Respectfully submitted,



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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Sam J. Milstein et al.

Serial No.: 09/760,307 Art Unit: 1615

Confirmation No.: 8759

Filed: January 11, 2001 Examiner: L. Channavajjala

For: ACTIVE AGENT TRANSPORT SYSTEMS

MARK-UP FOR AMENDMENT PURSUANT TO 37 C.F.R. 1.121

Hon. Commissioner of
Patents and Trademarks
Washington, DC 20231

September 28, 2001

Sir:

CLAIMS:

6. (Amended) A method as defined in claim 5, wherein said biologically-active agent is selected from the group consisting of human growth hormone, bovine growth hormone, growth hormone-releasing hormone, an interferon, interleukin-II,

insulin, heparin, calcitonin, erythropoietin, atrial naturetic factor, an antigen, a monoclonal antibody, somatostatin, adrenocorticotropin, gonadotropin releasing hormone, oxytocin, vasopressin, cromolyn sodium, vancomycin, desferrioxamine (DFO), low molecular weight heparin, antimicrobials, or any combination of any of the foregoing.

16. (Amended) A method as defined in claim 15, wherein said biologically-active agent is selected from the group consisting of human growth hormone, bovine growth hormone, growth hormone-releasing hormone, an interferon, interleukin-II, insulin, heparin, calcitonin, erythropoietin, atrial naturetic factor, an antigen, a monoclonal antibody, somatostatin, adrenocorticotropin, gonadotropin releasing hormone, oxytocin, vasopressin, cromolyn sodium, vancomycin, desferrioxamine (DFO), low molecular weight heparin, antimicrobials, or any combination of any of the foregoing.

25. (Amended) A composition as defined in claim 24, wherein said biologically-active agent is selected from the group consisting of human growth hormone, bovine growth hormone, growth hormone-releasing hormone, an interferon, interleukin-II, insulin, heparin, calcitonin, erythropoietin, atrial naturetic factor, an antigen, a monoclonal antibody, somatostatin, adrenocorticotropin, gonadotropin releasing hormone, oxytocin, vasopressin, cromolyn sodium, vancomycin,

desferrioxamine (DFO), low molecular weight heparin, antimicrobials, or any combination of any of the foregoing.

43. (Amended) A method as defined in claim 42, wherein said biologically-active agent is selected from the group consisting of human growth hormone, bovine growth hormone, growth hormone-releasing hormone, an interferon, interleukin-II, insulin, heparin, calcitonin, erythropoietin, atrial naturetic factor, an antigen, a monoclonal antibody, somatostatin, adrenocorticotropin, gonadotropin releasing hormone, oxytocin, vasopressin, cromolyn sodium, vancomycin, desferrioxamine (DFO), low molecular weight heparin, antimicrobials, or any combination of any of the foregoing.

53. (Amended) A method as defined in claim 52, wherein said biologically-active agent is selected from the group consisting of human growth hormone, bovine growth hormone, growth hormone-releasing hormone, an interferon, interleukin-II, insulin, heparin, calcitonin, erythropoietin, atrial naturetic factor, an antigen, a monoclonal antibody, somatostatin, adrenocorticotropin, gonadotropin releasing hormone, oxytocin, vasopressin, cromolyn sodium, vancomycin, desferrioxamine (DFO), low molecular weight heparin, antimicrobials, or any combination of any of the foregoing.

62. (Amended) A composition as defined in claim 61, wherein said biologically-active agent is selected from the group consisting of human growth hormone, bovine growth hormone, growth hormone-releasing hormone, an interferon, interleukin-II, insulin, heparin, calcitonin, erythropoietin, atrial naturetic factor, an antigen, a monoclonal antibody, somatostatin, adrenocorticotropin, gonadotropin releasing hormone, oxytocin, vasopressin, cromolyn sodium, vancomycin, desferrioxamine (DFO), low molecular weight heparin, anitmicrobials, or any combination of any of the foregoing.

80. (Amended) A method as defined in claim 79, wherein said biologically-active agent is selected from the group consisting of human growth hormone, bovine growth hormone, growth hormone-releasing hormone, an interferon, interleukin-II, insulin, heparin, calcitonin, erythropoietin, atrial naturetic factor, an antigen, a monoclonal antibody, somatostatin, adrenocorticotropin, gonadotropin releasing hormone, oxytocin, vasopressin, cromolyn sodium, vancomycin, desferrioxamine (DFO), low molecular weight heparin, antimicrobials, or any combination of any of the foregoing.

90. (Amended) A method as defined in claim 89, wherein said biologically-active agent is selected from the group consisting of human growth hormone, bovine growth hormone, growth hormone-releasing hormone, an interferon, interleukin-II, insulin, heparin, calcitonin, erythropoietin, atrial naturetic factor, an

antigen, a monoclonal antibody, somatostatin, adrenocorticotropin, gonadotropin releasing hormone, oxytocin, vasopressin, cromolyn sodium, vancomycin, desferrioxamine (DFO), low molecular weight heparin, antimicrobials, or any combination of any of the foregoing.

99. (Amended) A composition as defined in claim 98, wherein said biologically-active agent is selected from the group consisting of human growth hormone, bovine growth hormone, growth hormone-releasing hormone, an interferon, interleukin-II, insulin, heparin, calcitonin, erythropoietin, atrial naturetic factor, an antigen, a monoclonal antibody, somatostatin, adrenocorticotropin, gonadotropin releasing hormone, oxytocin, vasopressin, cromolyn sodium, vancomycin, desferrioxamine (DFO), low molecular weight heparin, antimicrobials, or any combination of any of the foregoing.